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Senate Bill 51

By: Senators Burke of the 11th, Watson of the 1st, Hufstetler of the 52nd, Millar of the 40th, Miller of the 49th and others

A BILL TO BE ENTITLED AN ACT

- 1 To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
- 2 pharmacists and pharmacies, so as to provide for substitutions of interchangeable biological
- 3 products; to define certain terms; to provide for requirements and limitations; to provide for
- 4 related matters; to repeal conflicting laws; and for other purposes.

5 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

6 SECTION 1.

- 7 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
- 8 pharmacies, is amended by revising Code Section 26-4-5, relating to definitions, by adding
- 9 new paragraphs as follows:
- 10 "(1.1) 'Biological product' means a biological product as defined in subsection (i) of
- section 351 of the Public Health Service Act (42 U.S.C. Section 262)."
- 12 "(18.2) 'Interchangeable biological product' means a biological product that the United
- States Food and Drug Administration has determined meets the standards set forth in
- subsection (k)(4) of 42 U.S.C. Section 262, or has been deemed therapeutically
- equivalent by the United States Food and Drug Administration."

16 SECTION 2.

- 17 Said chapter is further amended by revising Code Section 26-4-81, relating to substitution
- 18 of generic drugs for brand name drugs, as follows:
- 19 "26-4-81.
- 20 (a) In accordance with this Code section, a pharmacist may substitute:
- 21 (1) A a drug with the same generic name in the same strength, quantity, dose, and dosage
- form as the prescribed brand name drug product which is, in the pharmacist's reasonable
- professional opinion, pharmaceutically equivalent; or
- 24 (2) A biological product with an interchangeable biological product.
- 25 (b) If a practitioner of the healing arts prescribes:

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26 (1) A a drug by its generic name, the pharmacist shall dispense the lowest retail priced

- drug product which is in stock and which is, in the pharmacist's reasonable professional
- opinion, pharmaceutically equivalent; or
- 29 (2) A biological product by its nonproprietary name, the pharmacist shall dispense the
- 30 lowest retail priced interchangeable biological product which is in stock.
- 31 (c) Substitutions as provided for in subsections (a) and (b) of this Code section are
- authorized for the express purpose of making available to the consumer the lowest retail
- 33 priced:
- 34 (1) Drug drug product which is in stock and which is, in the pharmacist's reasonable
- professional opinion, both therapeutically equivalent and pharmaceutically equivalent:
- 36 <u>or</u>
- 37 (2) Interchangeable biological product which is in stock.
- 38 (d)(1) Whenever a substitution is made, the pharmacist shall record on the original
- prescription the fact that there has been a substitution and the identity of the dispensed
- drug product or interchangeable biological product and its manufacturer. Such
- 41 prescription shall be made available for inspection by the board or its representative in
- 42 accordance with the rules of the board.
- 43 (2) If a pharmacist substitutes a generic drug product for a brand name prescribed drug
- product when dispensing a prescribed medication, the brand name and the generic name
- of the drug product, with an explanation of 'generic for (insert name of brand name
- prescribed drug product)' or similar language to indicate substitution has occurred, must
- appear on the prescription label and be affixed to the container or an auxiliary label,
- unless the prescribing practitioner indicated that the name of the drug may not appear
- upon the prescription label; provided, however, that this paragraph shall not apply to
- 50 medication dispensed for in-patient hospital services or to medications in specialty
- 51 packaging for dosing purposes as defined by the board.
- 52 (3) If a pharmacist substitutes an interchangeable biological product for a prescribed
- 53 <u>biological product when dispensing a prescribed medication, the name of the</u>
- 54 <u>interchangeable biological product, with an explanation of 'interchangeable biological</u>
- 55 product for (insert name of prescribed biological product)' or similar language to indicate
- substitution has occurred, must appear on the prescription label and be affixed to the
- 57 <u>container or an auxiliary label, unless the prescribing practitioner indicated that the name</u>
- of the biological product may not appear upon the prescription label; provided, however,
- 59 <u>that this paragraph shall not apply to biological products dispensed for in-patient hospital</u>
- services or to biological products in specialty packaging for dosing purposes as defined
- 61 <u>by the board.</u>

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62 (e) The substitution of any drug <u>or biological product</u> by a registered pharmacist pursuant

- to this Code section does not constitute the practice of medicine.
- 64 (f) A patient for whom a prescription drug or biological product order is intended may
- 65 instruct a pharmacist not to substitute a generic name drug in lieu of a brand name drug or
- an interchangeable biological product in lieu of a prescribed biological product.
- 67 (g) A practitioner of the healing arts may instruct the pharmacist not to substitute a generic
- 68 name drug in lieu of a brand name drug <u>or an interchangeable biological product in lieu of</u>
- 69 <u>a prescribed biological product</u> by including the words 'brand necessary' in the body of the
- 70 prescription. When a prescription is a hard copy prescription drug <u>or biological product</u>
- order, such indication of brand necessary must be in the practitioner's own handwriting and
- shall not be printed, applied by rubber stamp, or any such similar means. When the
- prescription is an electronic prescription drug <u>or biological product</u> order, the words 'brand
- necessary' are not required to be in the practitioner's own handwriting and may be included
- on the prescription in any manner or by any method. When a practitioner has designated
- brand necessary' on an electronic prescription drug or biological product order, a generic
- drug <u>or interchangeable biological product</u> shall not be substituted without the practitioner's
- express consent, which shall be documented by the pharmacist on the prescription and by
- 79 the practitioner in the patient's medical record.
- 80 (h) Within a reasonable time following the dispensing of a biological product, the
- 81 <u>dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the</u>
- 82 specific product provided to the patient, including the name of the biological product and
- 83 the manufacturer. The communication shall be conveyed by making an entry into an
- 84 <u>interoperable electronic medical records system or through electronic prescribing</u>
- 85 <u>technology or a pharmacy record that is electronically accessible by the prescriber.</u>
- 86 Otherwise, the pharmacist shall communicate the biological product dispensed to the
- 87 prescriber, using facsimile, telephone, electronic transmission, or other prevailing means,
- 88 provided that communication shall not be required where:
- 89 (1) There is no FDA-approved interchangeable biological product for the prescribed
- 90 <u>product; or</u>
- 91 (2) A refill prescription is not changed from the product dispensed on the prior filling of
- 92 <u>the prescription.</u>
- 93 (i) The State Board of Pharmacy shall maintain a link on its website to the current list of
- 94 <u>all biological products determined by the federal Food and Drug Administration to be</u>
- 95 interchangeable with a specific biological product."

96 **SECTION 3.**

97 All laws and parts of laws in conflict with this Act are repealed.